

REMARKS

In the Final Office Action dated April 15, 2009, the Examiner's substantive rejections were all based at least in part on the Evans (U.S. Patent No. 5,924,074) and Dorne (U.S. Patent No. 5,325,293) references. Accordingly, the comments below regarding Evans and Dorne may be applicable to most, if not all, of the Examiner's rejections. Specifically, the Examiner rejected:

- Claims 104-111, 113-116, 118-122, 123-124, 126-128, 129, 130, 132, 134-136, 139-140, 142, 148-149, 152, and 153-154 under 35 U.S.C. §103(a) as allegedly being unpatentable over Evans in view of Dorne;
- Claims 112, 131, 138, 141, 144-146, 150-151, and 155-156 under 35 U.S.C. §103(a) as allegedly being unpatentable over Evans in view of Dorne and Peters et al. (U.S. Patent No. 5,893,098);
- Claims 117 and 147 under 35 U.S.C. §103(a) as allegedly being unpatentable over Evans and Dorne, and further in view of Official Notice;
- Claims 125 and 135-137 under 35 U.S.C. §103(a) as allegedly being unpatentable over Evans and Dorne as applied to claims 104, 106, and 123, and further in view of Letzt et al. (U.S. Patent No. 5,612,869);
- Claim 134 under 35 U.S.C. §103(a) as allegedly being unpatentable over Evans and Dorne as applied to claim 123, and further in view of Kraftson et al. (U.S. Patent No. 6,151,581); and
- Claims 142-143 under 35 U.S.C. §103(a) as allegedly being unpatentable over Evans and Dorne as applied to claims 104 and 106, and further in view of Peters et al. (U.S. Patent No. 5,893,098).

Applicant respectfully requests reconsideration of the use of Evans and Dorne in this regard. With all due respect, the Examiner's comments on pages 2-16 of the Office Action are not sufficient to carry the Patent Office's burden to establish a *prima facie* case of obviousness based on the Evans and Dorne references in rejecting Applicant's claims. That deficiency is a direct consequence of the insufficiencies of Evans and Dorne in that regard.

Among other things, Applicant respectfully submits that neither Evans nor Dorne nor their combination discloses or suggests at least the claimed features of means of generating new data. Instead, Evans and Dorne merely teach a means of compiling existing data. As further explained below, Applicant respectfully submits that the Examiner's rejections of Applicant's claims as obvious over Evans and Dorne are improper.

Among other things, Applicant respectfully submits that the Examiner's combination of those two primary references (Evans and Dorne) is improper and/or does not support the conclusions asserted by the Examiner. In that regard, the Office Action itself acknowledges at least some of the shortcomings of Evans: "Evans fails to expressly disclose an electronic means including a processing means for calculating intermediate values based on said recorded information and a processing means for using said intermediate values to generate said billing code." (see Office Action at page 4, para. 1).

It is illuminating to examine some of the reasons for Evans' admitted failure to disclose those elements (which comprise at least two elements of various of the rejected claims): (1) the calculation of Evaluation and Management (E&M) billing codes based on information collected from the physician during the patient encounter; and (2) using the same information that was collected during the patient encounter to generate the E&M billing codes. At best, Evans does not "calculate" anything, and Applicant respectfully submits that, because it does no calculations,

Evans cannot be prior art with respect to the instant Application. Evans certainly does not undertake the complex tasks of (1) collecting patient data at the point of care and (2) calculating intermediate and final billing codes based on that information collected about the patient at the point of care. In fact, Evans never uses the terms "intermediate," "final," or any similar terms to show that Evans could have even envisioned the concepts of the instant Application.

In contrast, the Applicant's invention makes complex computations based on the level of detail of three major components of a patient/physician encounter—(1) the patient history, (2) physical examination, and (3) medical decision making. These "intermediate" codes generate values that are combined (or otherwise processed in the "calculation" with other factors, such as the length of time of the patient encounter, which factor can override the intermediate code calculations, to compute a final code. Along with calculating that final Code, the instant application provides sufficient documentation to support the final Code.

The attempted combination of Evans with Dorne does not address the aforementioned shortcomings. The Office Action cites Dorne as disclosing "an apparatus for correlating billing codes with medical procedures comprising: an electronic means including a processing means for calculating intermediate values based on said recorded information (Fig. 1, col. 3 lines 18-38, col. 20-46) and a processing means for using said intermediate values to generate said billing code (Fig. 1, col. 3 lines 18-38, col. 20-46)." Applicant respectfully submits that this is a misreading of Dorne and/or an improper application of that reference. As set forth in detail below, the Examiner apparently has misunderstood Dorne's "apparatus for correlating billing codes with medical procedures" (to the extent that the Examiner asserts that Dorne is applicable to Applicant's inventions).

First, as with Evans, Dorne does not calculate anything. Dorne's summary of invention states that: "The present invention comprises a system and a method for correlating [not calculating] medical procedures into billing codes." (Column 3, lines 1-20) In this regard, Dorne makes clear that his invention relates solely to medical procedures: "The AMA has structured the CPT (Current Procedural Terminology) coding system into five main procedure rubrics: (1) Medicine; (2) Anesthesia; (3) Surgery; (4) Radiology; and (5) Pathology." (Column 1, lines 32-33) Dorne's disclosure is limited to these five sections of the CPT. Dorne focuses throughout its disclosure on the procedures used by radiologists, emphasizing the Surgery and Radiology sections of the CPT manual. However, the American Medical Association (AMA) has structured the CPT coding system into six total sections: the five identified by Dorne and an additional section, the Evaluation & Management (E&M) codes, which is actually the first section of the CPT manual. While Dorne deals solely with the five procedural sections, the instant application deals solely with the sixth section (the one NOT cited by Dorne): the Evaluation & Management Codes. The reason that this distinction is so critical is that only the E&M Codes require the complex calculations set forth in Applicant's invention.

The shortcomings of Dorne with respect to the instant inventions can be further explained by way of example. Under Dorne's technology, the physician performs a procedure on (or relating to) a patient, such as a diagnostic test or a surgical intervention. Each test or surgical intervention has an actual number in the CPT coding guideline. When billing for that procedure, the physician (such as radiologists, for example) lists each actual procedure code, using the codes listed in the CPT book that, as discussed above, are chosen by the Dorne-practicing radiologist only from the five (5) "procedure" sections of the CPT book - not from the E&M Codes to which the instant invention is directed.

Although Dorne discloses that the codes can be “combined” together (in a way that complies with billing regulations), Dorne does not involve any “calculation”. More specifically, Dorne discloses a method for “combining” individual procedure codes in such a way as to determine the final coding. In Dorne, the radiologist knows what procedure needs to be done, and knows the “raw code” for the procedure (from the five “procedure” sections of the CPT book). For example, if the patient has a heart problem, the radiologist knows that a radiological procedure will be performed to visualize the arteries in and around the heart. Accordingly, the raw code for each procedure, for example each blood vessel that is visualized, is known and does not have to be constructed. The physician immediately knows what procedure he or she is performing and enters the corresponding raw code. Dorne simply helps the physician, if necessary, list these known raw codes in such a way as to comply with billing requirements. Thus, the physician using Dorne must enter the raw CPT procedure codes, and Dorne “combines” these codes to comply with billing requirements.

In contrast with Dorne, the physician using the preferred embodiments of Applicant’s invention does not have to enter any codes in order to practice the invention. Rather, the physician simply enters data about the patient encounter (i.e., family and medical history, details of the patient’s personal history, blood pressure or other details of the physical examination, medications prescribed, etc.). Based on the raw data entered by the physician (as opposed to the raw “CPT codes” that Dorne requires), the present application, through a series of complex calculations, determines the appropriate final Evaluation & Management code, something neither needed nor envisioned by Dorne.

Thus, in contrast to Dorne, the present inventions allow the health care worker (who does not know in advance what the E&M raw code is) to determine the E&M raw code (which

determination can only be accomplished by means of a complicated calculation process). In fact, the health care worker using the present inventions cannot know in advance the E&M raw code, because E&M codes pertain to an encounter between a patient and a physician (or other health care worker) in which the health care worker does not and often cannot know ahead of time what questions will need to be asked, what kind of physical examination will need to be performed, what kinds of considerations will go into treating the patient, etc. The final raw code depends on the complexity of the evaluation, i.e., the amount of details obtained in the history, the number of body parts or functions assessed in the physical examination, and the number of elements involved in the physician's thought processes that are part of medical decision-making. The present invention discloses and claims methods of simplifying the complex process of determining that E&M code (the one NOT disclosed/discussed in Dorne) by generally prompting, guiding, and soliciting information/data for recording and processing information, and then calculating an associated raw code for billing purposes.

Accordingly, even if Applicant were to concede that "it would have been obvious ... to include the features of Dorne within the apparatus of Evans ... [to] rapidly and simply correlat[e] CPT codes with medical procedures performed during patient examination" (a point that Applicant does not concede, but which Applicant does not need to concede in the present context), as set forth above, that asserted "combination" of Evans and Dorne does not aid one of ordinary skill in the art in navigating and/or calculating the highly complex intermediate and final E&M billing codes as disclosed and claimed in Applicant's application.

In addition, Applicant respectfully submits that although Evans discloses at col. 16 lines 2-20, a means to capture data once data exists, Evans fails to disclose or suggest a means of generating the data. Applicant respectfully submits that Evans' data capture means is a "black

box”. In other words, Evans is aware that Clinical Data Capture and Progress Notes (see Evans’ Fig. 10) exist, but does not disclose HOW to generate them (see also Evans, col. 6, lines 10-36). Although Evans does disclose a means of collecting data such as the data described in Applicant’s disclosure, he does not disclose a means of generating that data. As shown in Evans’ Figure 7, a glucose result of 88 mg/dl (i.e., an existing result) is displayed for the particular patient with no disclosure for how that value of 88 mg/dl was determined/calculated. At most, Evans discloses entering previously collected data into the system at col. 6, lines 14-36: “During a patient visit, the healthcare provider (not shown) can enter, review and annotate patient information...clinical data obtained during the visit...diagnoses and procedures administered to the patient.” Thus, the healthcare provider does all the work to generate/determine unknown data, such as a diagnoses, and then simply enters it into Evan’s system. Accordingly, Applicant respectfully submits that Evans fails to anticipate or render obvious Applicant’s claimed inventions since Evans fails to teach a means of determining or generating unknown data (or helping to lead the healthcare provider toward generating/gathering that data, as further discussed below).

Further in that regard, Applicant respectfully submits that Evans’ Figures 9 and 24 do not show Applicant’s claimed practice guidelines, as asserted by the Examiner at page 3, line 1 of the Final Office Action. Among other things, although Evans does suggest at col. 7 line 40 to col. 8 line 17, an “optional practice guideline”, Evans’ practice guideline merely “provides references for practitioners to consult regarding courses of action to obtain a diagnosis and alternative treatments” (see Evans at col. 7, l. 55-57). In other words, Evans’ teaches only to provide digital textbooks/summaries or the like for practitioners to consult when diagnosing a patient, but does

not actually teach providing an algorithm in order to obtain a diagnosis, as provided by Applicant's claimed inventions.

Furthermore, at col. 11, l. 36-64, Evans explicitly states that the physician selects "the appropriate system and the diagnosis module 300 enters the selected system in the system box 332 and provides a list having specific diagnosis codes. The physician then selects the appropriate diagnosis code". Therefore, the physician must determine the appropriate diagnosis by selecting a choice from a list of possible diagnoses, as Evans fails to disclose an apparatus that is capable of determining a diagnosis. In other words, Evans does not teach how to arrive at a diagnosis, but rather how to place a list of possible diagnoses on a screen by selecting the appropriate parameters.

Applicant's invention, on the other hand, provides "guiding means" to generate new data (such as a diagnosis) that does not exist prior to a patient-physician encounter. For example, Applicant's guiding means prompts a physician to ask specific questions of the patient or perform specific tests, until the results of those inquiries can be narrowed down to generate a diagnosis or similar conclusion. In that regard, Applicant's system works in real-time to update the next prompt for guiding the physician based on the results of the previous inquiry. Evans' system, however, is not capable of guiding a physician to obtain specific results in order to generate a diagnosis/conclusion. Instead, as discussed above, Evans merely discloses entering existing data into the system, wherein that existing data is gathered by the physician of his own accord, independently of any guidance from the system.

Further in that regard and possibly related to the foregoing, Applicant respectfully sets forth below an example from daily life in an effort to emphasize the distinction between Applicant's invention and Evans and Dorne.

Imagine going to McDonald's to buy food. Assume that a Big Mac costs \$2.69. One option might be to get an Extra Value Meal. Another would be to buy menu items individually. In the latter, if someone wanted to get a Big Mac alone, the price would be \$2.69. If they order a medium fries alone, the price is \$1.59. If they order a medium drink alone, the price is \$1.49. Therefore, the price of the three individual items together would be \$6.18. However, if they ordered an Extra Value Meal, they would get a Big Mac, a medium fries, and a medium drink for just \$4.89.

Evans and Dorne envision a similar process: a number of separate items are entered, and a decision is made about the combination. In the case of McDonald's, the decision is what to charge – or in this case, how much to discount – for the combination. In the case of Evans and Dorne, the decision is how to document or deliver medical care, or how to bill based on the group of items. However, Applicant respectfully submits that knowing the pricing for the combination of menu items at McDonald's – whether for an Extra Value Meal or a Happy Meal – does not make it possible to know the ingredients that go into a Big Mac.

Analogously, Evans teaches at col. 6, lines 18-21 that a healthcare provider can likewise enter, review and annotate clinical data, such as body temperature and blood pressure, obtained during a patient visit. Nowhere, however, does Evans teach *how* a caregiver will know that they should take body temperature or blood pressure. Similarly, Evans lists the results of laboratory tests in Figure 7, an x-ray in Figure 8, and diagnoses and procedures in Figure 20, but does not teach *how* a caregiver will know to obtain the values listed. Applicant's invention, however, teaches *how* a provider can be assisted to arrive at those values.

Likewise, Dorne teaches accumulating all of the relevant CPT (Current Procedural Terminology) codes pertinent to a procedure performed, and then applying the billing rules to

determine which numerical code determines the final bill. For example, an examination of the left vertebral artery would require codes 36216 and 75685 (Dorne, col. 1, l. 50-57). However, when multiple vessels are examined during a procedure, each vessel may have a raw code associated with it, and the final bill will be based on the smallest vessel examined, for example, a third order vessel (Dorne, col. 2, l. 10-16 and Fig. 10). In this example, Dorne teaches that the numerical code for each vessel examined should be included in the final description, but the final bill is based only on the third order vessel. Thus, Dorne's grouping of CPT codes to arrive at a final code is the equivalent of combining a Big Mac, a medium fries, and a medium soft drink to create an Extra Value Meal (from Applicant's McDonald's example above). Applicant's invention, on the other hand, teaches how to make a Big Mac.

Furthermore, in contrast with Applicant's invention, Dorne teaches that certain entries are based on subjective parameters decided by the user (Dorne, col. 7, l. 67 – col. 8, l. 9 and Figs. 6A and 6B). In other words, Dorne is not silent with respect to selecting parameters. In fact, Dorne expressly discloses that there are no objective criteria used to determine what parameters to select. Instead, the user/physician is expected to enter a parameter, such as "Focused H&P" or "Straightforward Decision", based on his subjective opinion/expertise. Applicant's invention, on the other hand, provides objective criteria to determine what parameters to select.

In summary, Evans and Dorne teach how to compile parameters only after they have been identified. Applicant's system, on the other hand, teaches how to arrive at the parameters. Accordingly, neither Evans nor Dorne, nor any permissible combination of the two references anticipate or render obvious Applicant's claimed inventions.

Furthermore, Applicant respectfully submits that the addition of Letzt (or any other prior art of which Applicant is aware) to the Evans and Dorne combination does not address the foregoing

shortcomings of Evans and Dorne. In addition to the remarks set forth above, Applicant notes that the Office Action asserts that Letzt discloses “a timer for tracking total time and patient counseling time including a Health Care Financial Administration billing code” (see Office Action at page 13, para. 7). Applicant respectfully notes that Letzt does not teach a timer of this type at col. 26, lines 12-28. Instead, the Letzt “timer”, simply put, is an alarm clock that tells people when to take their medication or other treatment. Letzt clearly describes an alarm clock in the Abstract: “The user device generates voice messages to remind a user when and how to take or refill prescribed medications, to attend to other health matters, and to keep doctor’s appointments.”, and at column 1, lines 6-24: “This invention relates generally to prompting devices, and more particularly to devices for prompting a user to take medication, or to perform other health care related actions, at or sufficiently close to prescribed times”. Nowhere does Letzt disclose or suggest recording the passage of ANY interval of time (such as the time spent by a provider in a specific patient encounter), recording the total patient counseling time, and determining what fraction counseling constitutes of the total time of the encounter. This is required by the billing codes in order to determine how to bill for certain encounters in Applicant’s inventions. Nowhere does Letzt describe tracking time for any purposes (such as for generating a billing code). Accordingly, Applicant respectfully submits that none of the prior art, alone or in any permissible combination, discloses or renders obvious any of Applicant’s claimed inventions.

Applicant respectfully submits that the discussion above with regards to the combination of the two primary references (Evans and Dorne) is not intended to concede on any point with regards to any of the other cited references (Peters, Kraftson, Letzt, Official Notice, and any other prior art of which Applicant is aware). Applicant’s discussion above is directed to the Evans and Dorne references since the Examiner’s substantive rejections were all based at least in part on the

combination of those two references. Accordingly, the comments above regarding Evans and Dorne may be applicable to most, if not all, of the Examiner's rejections.

Applicant respectfully requests the opportunity to further review this point with the Examiner and his supervisor, prior to putting Applicant and the Patent Office to the expense of an appeal and/or further prosecution filings.

Accordingly, Applicant respectfully submits that response is sufficient to address all the pending rejections of the claims. Moreover, Applicant respectfully submits that Applicant's claims are in condition for allowance as currently pending, notice whereof is respectfully requested of the Examiner.

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If the Examiner would like to discuss any remaining or new issues regarding this communication, the Examiner is invited to contact the undersigned representative of Applicant at (949) 718-6750.

Respectfully submitted,

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